UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY) MDL No. 1456
AVERAGE WHOLESALE PRICE) Master File No. 01-12257-PBS
LITIGATION) Subcategory Case No. 06-11337 -PBS
) (Doc. No. 5871 in Case No. 01-12257
THIS DOCUMENT RELATES TO:) Hon. Patti B. Saris
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Abbott Laboratories,) LEAVE TO FILE GRANTED ON) JUNE 10, 2009
Inc.,)
)
Civil Action No. 06-11337-PBS.)

UNITED STATES' MOTION FOR LEAVE (GRANTED ON JUNE 10, 2009) AND INCORPORATED RESPONSE TO ABBOTT'S OBJECTION TO MAGISTRATE BOWLER'S ORDER CONCERNING RFAS

The United States of America, through undersigned counsel, respectfully seeks leave to file a response to Abbott's Objection to Abbott's Motion to Compel Sufficient Responses to Abbott's Request for Admission ("Abbott's RFA Objection") (Docket No. 5827) pursuant to Fed. R. Civ. P. 72(a).

The United States' response to Abbott's RFA Objection is incorporated herein:

RESPONSE TO ABBOTT'S RFA OBJECTION

BACKGROUND

Abbott served its 175 RFA requests¹ upon the United States on December 1, 2007. The United States timely served its extensive responses and objections to the RFAs in February 2008. The parties met and conferred and did not reach resolution to Abbott's concerns about the United

¹RFAs 1 to 69 contained multiple subparts.

States' RFA responses. Thereafter, on March 31, 2008, Abbott filed and served its motion to compel sufficient responses to its RFAs (RFA Motion to Compel), to which the United States responded on April, 25 2008. Abbott did not seek leave to file a reply. The response of the United States (D.E. 5256) to Abbott's Motion to Compel is incorporated by reference herein. The United States objected on, among other grounds, the relevance of these pre-1991 documents that do not pertain to Abbott drugs; the failure of Abbott to properly seek authentication of the documents, rather than seeking to establish their admissibility; and the fact that Abbott sought to have select quotes from documents admitted from documents that may never be admissible in an attempt to circumvent the Rules of Evidence.

Magistrate Bowler held a hearing on Abbott's motion to compel on December 4, 2008, ordering the United States to provide amended responses to certain RFAs while denying other relief on other RFAs sought by Abbott. For purposes of this Response and Abbott's RFA Objection, the RFAs that are at issue are RFAs 1-28 and RFAs 144 to 166, which concern matters predating the claims period of 1991 to 2001 in this case. This Court had previously limited the scope of discovery propounded by the United States upon Abbott to that 1991 to 2001 claims period.

LEGAL STANDARD FOR REVIEW OF A MAGISTRATE JUDGE BOWLER'S NON-DISPOSITIVE DISCOVERY ORDER

Abbott objects to a non-dispositive order denying it relief on a discovery matter in this case. Pursuant to Fed. R. Civ. P. 72(a), when a party files a timely objection to a magistrate judge's order, a district court will modify or set aside any part of the order that is clearly

erroneous or contrary to law. *See* 28 U.S. 636(b)(1)(A); *Riggs v. Peschong*, 2008 WL 1995453, at *2, (D. N.H. May 6, 2008)(J. DiClerico). In determining whether a magistrate judge's order is "clearly erroneous", a district court must assess whether "after scrutinizing the entire record [the district court] form[s] a strong, unyielding belief that a mistake has been made." *Phinney v. Wentworth Douglas Hosp.*, 199 F.3d 1, 4 (1st Cir. 1999). In making such an evaluation, the district court's review is limited to the arguments presented before the magistrate. *See Guillemard-Ginorio v. Contreras-Gomez*, 490 F.3d 31, 37 (1st Cir. 2007). No objection to a magistrate's non-dispositive order can be predicated upon new arguments not raised below before magistrate. *See id.*; *Peschong*, 2008 WL 1995453, at *2 (applying *Contreras-Gomez* holding in Rule 72(a) non-dispositive motion context).

DISCUSSION

At the outset, Abbott cannot contest Magistrate Judge Bowler's decision to limit the RFAs to the operative claim period of the case from 1991 until 2003 given that this is the time limitation placed upon discovery by this Court and Magistrate Judge Bowler in various orders in this case. (*See* e.g., Docket No. 4244, 4701, 4483). Judge Bowler's ruling was not clearly erroneous in that she was simply applying the Court's own prior limitation upon the parties' ability to seek discovery from one another on May 27, 2007. Seeking information predating 1991 is no less burdensome for the United States than it is for Abbott – perhaps more so. For the same reasons why Abbott should not be required to provide discovery information prior to 1991, it cannot insist that the United States research documents and information or statements predating 1991, in some instances dating back decades.

Abbott's argument that the information may inform matters within the operative period of the case also misses the mark. Some of Abbott's RFAs 1 to 28 and 144 to 166 concern government information and documents that go as far back as the 1960's and 1970's, or positions of the United States in the early to mid 1980's. Abbott fails to demonstrate how this dated information is relevant in showing the clear error of the Magistrate's order. Given the complexity of the authentication RFAs (1 to 28), and the research involved in tracking down individuals with knowledge dating back that far to research the truth of many of the statements set forth in RFAs 1 to 28 and 144 to 166, it would be inordinately burdensome for the United States to have to research and respond to these RFAs, even though they could be wholly irrelevant to this case.

Determining that there needs to be some limits upon discovery, this Court drew a clear demarcation for discovery in this case from 1991 to 2003. Here, Abbott is attempting to place limits on the ability of the United States to obtain discovery outside of this period *while at the same time seeking nearly unfettered discovery for Abbott itself regardless of burden or relevance considerations.* Abbott's RFA Objection fails to demonstrate how Judge Bowler committed clear error by foreclosing Abbott from doing so, especially without a showing that would outweigh the burden placed upon the United States that the discovery it seeks in these "pre-1991" RFAs concerns critical information relevant to the Subject Drugs for the claims period of 1991 through 2003. RFAs 1 to 28 and 144 to 166 on their face do not².

²These RFAs are aimed at establishing Abbott's construction of "government knowledge", however, Abbott makes no showing that the Magistrate clearly erred because these RFAs concern the Government's specific knowledge about Abbott's pricing of the Subject Drugs in this case. Certainly, the RFAs on their face do not reflect that they are targeted at such specific knowlege on the part of CMS/HCFA.

B. With Respect To RFAs 1-28, The Magistrate Judge's Ruling Was Not Clearly Erroneous As The United States Is Willing To Stipulate To The Authenticity Of These Documents Anyway, And Abbott Has Not Established that They Will Be Admitted At Trial.

Magistrate Judge Bowler, in ruling to limit RFAs 1-28 to the 1991 to 2003 time period did not commit clear error in view of the United States' willingness to stipulate to the authenticity (but not admissibility) of the documents referenced in these RFAs, if Abbott presents at trial a complete, proper copy of the exhibit. RFAs 1-28 purport to be "Authentication RFAs". If RFAs 1 to 28 are truly only authentication RFAs, then the United States' compromise by agreeing to stipulate to authenticity resolves the entire question.

Notwithstanding the labels Abbott gave them, and despite strict limits on the number of authentication versus non-authentication RFAs, Abbott added a series of subparts to RFAs 1 to 28, that appear to extend beyond mere authentication matters – seeking responses that appear directed at admissibility issues, and that seek to have the United States admit that certain quotations are contained in documents, which are not necessarily specific to the Abbott Subject Drugs³. Magistrate Judge Bowler's ruling is not clearly erroneous because these are not proper

³The United States checked the quoted language in each of the first 69 RFAs and fairly admitted or qualified the fact that those quotes were contained in the designated exhibit, to the extent possible. Some quotes represented spliced phrases and sentences from various fragmented places in a particular document (*i.e.*, RFAs 2, 6, 8-11, & 26); some just outright misquoted the cited language (*i.e.*, RFAs 4, 17). Further, Abbott cannot simply say that just because some statement may have been made by an employee or contractor employed by the U.S. Government, or a legislative representative, or such a statement is contained in a document that the statement constitutes a party admission by CMS for all purposes in this case. Informal understandings of agency officials concerning the meaning of a regulation are not relevant. In *United States v. Lachman*, the Court of Appeals held that any interpretive issue relating to a regulation is resolved through reference to the official public record. 387 F.3d 42, 54 (1st Cir. 2004). The "non-public understanding [of individual government officials] of the regulation do not remotely satisfy the requirements of formality and public accessibility" and are not entitled to any deference. *Id.*

uses of RFAs, especially for documents that have not been admitted into evidence.

Rule 36(a)(1)(B) permits RFAs targeted at the genuineness – not the admissibility --of the documents. Critically, a response to an RFA is an admission for all purposes in this case. (See Fed. R. Civ. P. 36(b)). The United States did respond to Abbott's convoluted authentication RFAs 1-28 to the extent it could, admitting or denying information outright, or with qualification as necessary. See Kaufman, 2006 WL 3969212, at *3 ("as a general matter, [the party opponent] acknowledges that it denied such requests because plaintiff was 'cherry-picking' statements out of context. . . . I will not compel additional answers to unspecified RFAs, nor would I compel a party to provide a substantive answer to an RFA that seeks ratification of an out-of-context, incomplete statement."); cf. Lewis v. Michaels Stores, Inc., 2007 WL 2021833, at *3 (M.D. Fla. Jul. 12, 2007)(disallowing objection deferring to document content as best evidence, where no additional attempt was made to respond to RFA). Abbott sought to compel a more complete response with respect to RFAs 1 to 28, without the United States' qualifications concerning the facts that the reference documents were not admitted into evidence yet and could be the subject of numerous objections at the time of trial.

Once a document is admitted into evidence, obviously, Abbott can attempt to read its content to the jury, subject to overcoming objections that may arise. *See Vons Companies, Inc. v. U.S.*, 51 Fed. Cl. 1, 14 (Ct. Cl. Nov. 6, 2001). In *Vons*, 51 Fed. Cl. at 14-15, the court made clear that if a party's RFAs seek to confirm quotes from documents that are irrelevant, "it follows, *a fortiori*, that the quoted portions thereof referenced in these requests are also irrelevant." If the documents are not admitted at trial, Abbott should not be permitted to use any admissions concerning the authentication of documents – nor does Abbott cite any authority for

the proposition that it can. The Rules of Evidence would have no purpose if a party could avoid the consequence of not being able to admit a document into evidence merely by quoting the language therein and seeking an admission that the quote existed in the document⁴.

C. Abbott's New Arguments Not Raised Before Magistrate Bowler Cannot Be Considered By This Court, And Fail In Any Event

Abbott apparently contends that Magistrate Judge Bowler erred in not ordering more specific answers to RFAs 1 to 28, and RFAs 144 to 166 because of the United States' designation of Dr. Theodore Marmor as a possible rebuttal witness in this case. While Dr. Marmor's report was served in June of 2008, after the Motion to Compel briefing, Abbott still could have raised this argument pre-hearing. Because this argument was not raised below, even though Abbott had approximately 6 months to do so before the December 2008 hearing, it is improper, as under the Rule 72 standard, this Court cannot consider *de novo* a new argument not raised before the Magistrate Judge in assessing the sole question before it – whether the Magistrate committed clear error. *See Guillemard-Ginorio v. Contreras-Gomez*, 490 F.3d at 37; *Peschong*, 2008 WL 1995453, at *2.

Moreover, even if *arguendo* Abbott had timely raised this argument before the Magistrate, it rings hollow. First, Dr. Marmor's testimony only will come into play in this case if necessary as a rebuttal witness at trial, primarily on the question of Abbott's government

⁴It is only at or near the time of trial that the relevance, hearsay and other admissibility objections will be resolved. By insisting that the United States respond to RFAs 1-28, Abbott is asking this Court to review the RFAs, and the related exhibits, and make determinations as to the *admissibility, not just the authentication* of the documents referenced in the RFAs. By disallowing Abbott's objections with respect to RFAs 1-28, Magistrate Judge Bowler did not clearly err for this additional reason – it is prudent to, at a minimum, wait until it is determined if the documents will be admitted into evidence before requiring a response to RFAs aimed at confirming that quoted language contained in it.

knowledge defense. Depending upon this Court's rulings concerning government knowledge and Abbott's decisions regarding its own experts, Dr. Marmor may never testify. If it is truly Abbott's contention that RFAs 1 to 28 and 144 to 166 are necessary (which the United States disputes) because of the possibility that Dr. Marmor may testify at trial,⁵ then the decision of whether to require further answers can be deferred until such time as it is determined that Dr. Marmor will testify, if at all, and the eventual scope of his testimony.

D. Alternatively, This Court Need Not Determine Abbott's RFA Objection Now

Alternatively, a decision to defer ruling on the RFAs also would be within the broad discretion this Court has to manage pretrial discovery. *See e.g. U.S. Steel v. DeMatteo Constr. Co.*, 315 F.3d 43, 53 (1st Cir. 2002) (management of pretrial discovery lies within the sound discretion of the trial court); *City of Waltham v. United States Postal Serv.*, 11 F.3d 235, 243 (1st Cir. 1993) (district court has broad power to control discovery and in doing so can weigh discovery burdens against likelihood of finding relevant material); *Lamoureux v. Genesis Pharmacy Services, Inc.*, 226 F.R.D. 154, 159 (D. Conn. 2004). Moreover, given the breadth of Abbott's RFAs, this Court is faced with having to spend exorbitant amounts of time delving into the minutiae of challenged responses and objections⁶ for RFAs 1 to 28 and 144 to 166, on a

⁵Notably, this argument on its face is contradicted by the fact that Abbott propounded its RFAs well before the United States designated Dr. Marmor as a possible rebuttal expert witness. Therefore, Abbott cannot claim prejudice to its ability to challenge Dr. Marmor's expert testimony because it did not craft its RFAs as a result of Dr. Marmor's designation.

⁶Such an exercise is premature and unnecessary until the trial court determines the various legal and factual matters that will be raised pretrial in various dispositive and *in limine* motions, including those dealing with government knowledge. Except possibly for document authentication purposes, which the United States will stipulate to, the form of RFAs 1 to 28 render them virtually meaningless on their own if the referenced documents in the RFAs are not admitted, and duplicative if the documents are.

request by request basis to determine whether the Magistrate clearly erred.

In evaluating the propriety of the Magistrate's order concerning Abbott's RFAs 1 to 28 and 144 to 166, this Court can determine that final disposition of Abbott's Objection be made at a pretrial conference or at a designated time prior to trial, which will permit this Court to hear and streamline the legal and factual issues in this case after dispositive motions are decided. The United States submits that the vast majority, or all, of the RFA responses at issue in Abbott's Objection could be rendered moot once this Court addresses the parties' anticipated motions for summary judgment concerning government knowledge, motions to strike defenses and motions *in limine*⁷. At a minimum, this Court may defer matters under Rule 36 on RFAs until a final pretrial conference is appropriate, if the parties will not experience prejudice. *See Bouchard v. U.S.*, 241 F.R.D. 72, 75-76 (D. Me. 2007).

CONCLUSION

Abbott has failed to demonstrate that Magistrate Judge Bowler committed clear error in upholding the United States' objections to those RFAs that concern matters outside of the operative period of this case, nor can Abbott make such a showing, particularly given this Court's prior ruling on Abbott's motion to limit discovery to 1991 through 2003.

WHEREFORE, based upon the foregoing, the United States respectfully requests that

⁷This Court's future rulings especially on any dispositive motions on Abbott's government knowledge defense, will likely profoundly impact, and/or moot many of the issues presented in Abbott's RFA Objection with respect to documents and government knowledge questions dating back decades before the operative claim period of 1991 to 2001. Should Abbott seek to use the RFA responses outside of the 1991 to 2003 time period of this case, in its summary judgment or other pretrial briefing, it can always cite to the underlying predicate evidence it contends supports the factual assertions. There would be no prejudice to the parties, as the RFA responses are largely trial tools.

this Court grant it leave to file the incorporated Response to Abbott's RFA Objection herein, and uphold Magistrate Judge Bowler's Order denying Abbott's Motion to Compel Different Responses concerning RFAs 1 to 28, and RFAs 144 to 166.

Respectfully submitted,

For the United States of America,

MICHAEL K. LOUCKS ACTING UNITED STATES ATTORNEY

George B. Henderson, II Assistant U.S. Attorney John Joseph Moakley U.S. Courthouse Suite 9200, 1 Courthouse Way Boston, MA 02210 (617) 748-3398 (617) 748-3272

JEFFREY H. SLOMAN ACTING UNITED STATES ATTORNEY SOUTHERN DISTRICT OF FLORIDA

/s/ Ann M. St. Peter-Griffith

Mark A. Lavine Ann M. St. Peter-Griffith June Acton Special Attorneys for the Attorney General 99 N.E. 4th Street, 3rd Floor Miami, FL 33132

Phone: (305) 961-9003 Fax: (305) 536-4101

Dated: June 18, 2009

TONY WEST ASSISTANT ATTORNEY GENERAL

/s/ Gejaa T. Gobena

Joyce R. Branda
Daniel R. Anderson
Renée Brooker
Justin Draycott
Rebecca Ford
Gejaa T. Gobena
Civil Division
Commercial Litigation Branch
P. O. Box 261

Ben Franklin Station Washington, D.C. 20044 Phone: (202) 307-1088 **CERTIFICATE OF SERVICE**

I hereby certify that I have this day caused an electronic copy of the above UNITED

STATES' MOTION FOR LEAVE AND INCORPORATED RESPONSE TO ABBOTT'S

OBJECTION TO MAGISTRATE B OWLER'S ORDER CONCERNING RFAS to be served

on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management

Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all

parties.

/s/ Ann M. St. Peter-Griffith

Dated: June 18, 2009

11